

### **REMARKS**

Claims 1-10 are now pending in the application. Claims 1-10 are amended herein. The Examiner is respectfully requested to reconsider and withdraw the rejections in view of the amendments and remarks contained herein.

### **NON-RESPONSIVE AMENDMENT**

The Office Communication mailed April 23, 2008 stated that the amendment filed February 21, 2008 canceling all claims drawn to the elected invention and presenting only claims drawn to a non-elected invention is non-responsive. Applicant respectfully disagrees and requests reconsideration of this finding based on the following.

The Office Action mailed November 23, 2007 rejected claims 1 – 10 under 35 USC § 112 for claiming a use without any active, positive steps delimiting how this use is actually practiced. Claims 1 – 10 were also rejected under 35 USC § 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process. The Examiner then elaborated that it is *unclear* if Applicant is intending to claim a RSM composition or a method of using RSM. The Examiner then concluded that “for the sake of examination, these claims will be examined as RSM composition claims”.

The Examiner’s alternative rejections under 35 USC § 112 and § 101 comply with the Office practice guidelines set forth in MPEP 2173.05(q). However, the Examiner’s subsequent prior art rejection of the claims fails to comply with the Office practice guidelines as set forth in MPEP 2173.06. More particularly, MPEP 2173.06 states that when the terms of a claim are considered to be indefinite, at least two

approaches to the examination of an indefinite claim relative to the prior art are possible. First, where the degree of uncertainty is *not great*, **and** where the claim is subject to more than one interpretation and at least one interpretation would render the claim unpatentable over the prior art, an appropriate course of action would be for the examiner to enter two rejections: (A) a rejection based on indefiniteness under 35 USC § 112; and (B) a rejection over the prior art based on the interpretation of the claims which renders the prior art applicable. Second, where there is a great deal of confusion and uncertainty as to the proper interpretation of the limitations of the claim, it would not be proper to reject such a claim on the basis of the prior art.

The Examiner followed the first approach and entered two rejections, the first under 35 USC § 112 and the second over the prior art. However, for the first possible approach to be proper, the degree of uncertainty must not be great. This is because a rejection based on prior art should not be based on speculation about the meaning of the terms employed in a claim or *assumptions that must be made as to the scope of the claims*. Here, the Examiner admitted that the claim scope was unclear. As such, great uncertainty existed.

More particularly, the Examiner offered two equally plausible interpretations of the scope of the claims: “it is unclear if Applicant is intending to claim a RSM composition or a method of using RSM”. Thus, the claim scope was unclear and uncertain. The Examiner emphasized the uncertainty in the Office Communication mailed April 23, 2008 by stating “it was unclear if ‘use’ indicated a composition or a method”. With both interpretations of claim scope equally possible, confusion and uncertainty existed as to the proper interpretation of the claims and the Examiner made

assumptions as to the scope of the claims. The rejection based on prior art was improper in view of the speculation regarding the scope of the claims.

Notwithstanding the great uncertainty of the scope of the claims, the Examiner assumed the claims to be RSM composition claims. The Examiner now takes the position that the method claims presented herein lack unity with the composition claims and concludes that since the Applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. However, Applicant did not elect either composition or method claims. Instead, the Examiner made an assumption, deemed the claims to be composition claims, and now attempts to deprive the Applicant of the opportunity to amend the claims.

Applicant did not originally present composition claims for prosecution. Applicant presented use claims. As the Examiner admitted, the use claims could be either composition claims or method claims. Applicant did not elect composition claims. The Examiner did. As stated in the Office Communication mailed April 23, 2008: since it was unclear if “use” indicated a composition or a method, the claims were examined as composition claims.

As set forth in 37 CFR 1.145, if, after an office action on an application, the applicant presents claims directed to an invention distinct from and independent of the invention *previously claimed*, the applicant will be required to restrict the claims to the invention *previously claimed*. The method claims presented herein are not distinct from nor independent of the invention *previously claimed*. Rather, the method claims presented herein are directed to one of the two alternatives the Examiner admitted were

*previously claimed.* Although the method claims presented herein are not composition claims as assumed by the Examiner, this is not what 37 CFR 1.145 requires. As such, election by original presentation is not applicable to the present situation.

It should also be noted that the method claims presented herein have unity of invention with the composition claims assumed by the Examiner. According to 37 CFR 1.475, the claims of a national stage application can relate to a group of inventions that form a single general inventive concept (unity of invention). The requirement of unity of invention is deemed fulfilled when there is a technical relationship involving one or more of the same or corresponding special technical features. 37 CFR 1.475(b) specifically states that “a product and a process of use of said product” will be considered to have unity of invention. Thus, the composition claims (i.e., product claims) and the method claims (i.e., process of use of said product) clearly have unity of invention.

The Examiner’s own prior art rejections show the unity of “a product and a process of use of said product” as set forth in 37 CFR 1.475(b). For example, while commenting on the composition claims, the Examiner states that Yan ‘651 teaches “using the composition to treat”. Later, the Examiner states that Yan ‘094 teaches “using the composition to treat”. The Examiner’s own comments evidence the interdependence and unity of the composition claims assumed by the Examiner and the corresponding method of use/treating claims presented herein.

It is important to note that the Office practice guidelines as set forth in MPEP 1850 mandate that a lack of unity of invention should be neither raised *nor maintained* on the basis of a narrow, literal or academic approach. Instead, there should be “a broad, practical consideration of the degree of interdependence of the alternatives

presented". According to MPEP 1850, the benefit of any doubt should be given to the applicant.

Finally, Applicant respectfully submits that the search and examination of the method claims presented herein can be made without serious burden and therefore in compliance with MPEP 803, the examiner must examine them on the merits, *even if* the method claims are directed to an independent or distinct invention. See MPEP 803.

#### **ELECTION/RESTRICTION**

Applicant acknowledges with thanks the Examiner's reconsideration of the species requirement and further acknowledges the finality of the same.

#### **INFORMATION DISCLOSURE STATEMENT**

Applicant acknowledges the Examiner's position with respect to the references cited by the applicant in the Information Disclosure Statement filed January 13, 2006. Applicant obtained copies of these references and submitted them to the office on February 21, 2008.

#### **REJECTION UNDER 35 U.S.C. § 112 AND § 101**

Claims 1-10 stand rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point and distinctly claim the subject matter which Applicant regards as the invention. Claims 1-10 stand rejected under 35 U.S.C. § 101 because the claimed recitation of a use results in an improper definition of a process. Claims 1-10 are amended herein to clearly recite a method of using RSM as a treatment

which comprises a step of administration. Accordingly, reconsideration and withdrawal of these rejections are respectfully requested.

### **REJECTION UNDER 35 U.S.C. § 102**

Claims 1-7, 9 and 10 stand rejected under 35 U.S.C. § 102(b) as being anticipated by Yan et al. (U.S. Pat. Pub. No. 2003/0152651). This rejection is respectfully traversed. Notwithstanding, claims 1-7, 9 and 10 are amended herein to clearly recite a method for treating anti-aspirin resistance in a subject. Since this rejection is based on the compositions disclosed by Yan '651 but the claims are directed to a method of treatment, reconsideration and withdrawal of this rejection are respectfully requested.

Claims 1-7, 9 and 10 stand rejected under 35 U.S.C. § 102(e) as being anticipated by Yan et al. (U.S. Pat. Pub. No. 2005/0037094). This rejection is respectfully traversed. As stated above, claims 1-7, 9 and 10 are amended herein to recite a method for treating anti-aspirin resistance in a subject. As with the rejection based on Yan '651, this rejection is based on the compositions disclosed by Yan '094. The claims, however, are directed to a method of treatment. As such, reconsideration and withdrawal of this rejection are respectfully requested.

Claims 1-7, 9 and 10 stand provisionally rejected under 35 U.S.C. § 102(e) as being anticipated by copending Application No. 10/903,110. This rejection is respectfully traversed. In view of the amendments to claims 1-7, 9 and 10 which now clearly recite a method for treating anti-aspirin resistance in a subject and not a composition, reconsideration and withdrawal of this rejection are respectfully requested.

### **REJECTION UNDER 35 U.S.C. § 103**

Claims 1 and 4-8 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Yan et al. (U.S. Pat. Pub. No. 2003/0152651). This rejection is respectfully traversed. Since this rejection is based on the compositions disclosed by Yan '651 but Claims 1-7, 9 and 10 are amended herein to clearly recite a method for treating anti-aspirin resistance in a subject, reconsideration and withdrawal of this rejection are respectfully requested.

### **DOUBLE PATENTING**

Claims 1-10 stand provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over Claims 114, 116-120 and 122-138 of copending Application No. 10/210,548. Applicant elects to defer filing a terminal disclaimer until after the Examiner considers the amendments set forth herein.

Claims 1-10 stand provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over Claims 1-9, and 11-24 of copending Application No. 10/903,110. Applicant elects to defer filing a terminal disclaimer until after the Examiner considers the amendments set forth herein.

### **CONCLUSION**

It is believed that all of the stated grounds of rejection have been properly traversed, accommodated, or rendered moot. Applicant therefore respectfully requests that the Examiner reconsider and withdraw all presently outstanding rejections. It is believed that a full and complete response has been made to the outstanding Office



Action and the present application is in condition for allowance. Thus, prompt and favorable consideration of this amendment is respectfully requested. If the Examiner believes that personal communication will expedite prosecution of this application, the Examiner is invited to telephone the undersigned at (248) 641-1600.

Respectfully submitted,

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